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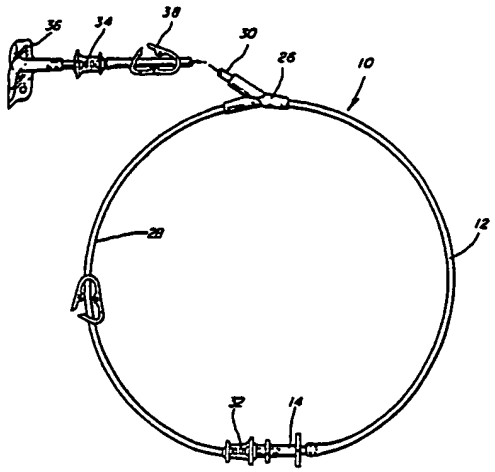
(54) Title: DETACHABLE PERITONEAL DIALYSIS SET



(57) Abstract

A peritoneal dialysis connection set comprises flexible tubing (12) including a central portion of the tubing having a free end. First connector means (14) are carried on the free end and adapted for removable, sealed, flow-through connection with tubing communicating with the peritoneal cavity of the patient. At least two lengths of branch tubing (28, 30) communicate with the central tubing portion, each of the lengths of branch tubing defining a free end and respectively carrying second and third connector means (32, 34) at the free ends. The second and third connector means are each adapted for removable, sealed, flow-through connection with a connector communicating with a dialysis solution container, and the first connector (14) is also adapted for removable, sealed connection with either of the second and third connectors (32, 34) in a storage mode of the set. The set can be reused for providing and removing peritoneal dialysis solution from the peritoneal cavity of a patient, and then may be returned to its storage mode and stored separate from the patient during the 'dwell' period of peritoneal dialysis therapy.

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DETACHABLE PERITONEAL DIALYSIS SET

Technical Field and Prior Art

Peritoneal dialysis is finding wide use for the maintenance of patients having end stage renal disease on a chronic basis, and also for various short term treatments. Typical modes of peritoneal dialysis include continuous ambulatory peritoneal dialysis (CAPD), continuous cycling peritoneal dialysis (CCPD) and intermittent peritoneal dialysis (IPD), all of which are in current clinical use.

Continuous ambulatory peritoneal dialysis is particularly popular, being one of the lowest cost dialysis techniques, and in which the patient is not tied to a machine, but instead is free to engage in normal activities throughout the entire day.

Patients have complained about one disadvantage of CAPD. They have to wear an empty dialysis solution bag and set connected to the peritoneal catheter under their clothing. This requirement results from the extreme sensitivity of CAPD patients to peritonitis, with the result that many physicians have felt it undesirable to remove the empty peritoneal dialysis solution bag and the transfer set which connects to the peritoneal dialysis catheter during the "dwell" period, i.e., that time in which the peritoneal dialysis solution is residing in the peritoneal cavity without being administered or drained, and during which time the dialysis exchange is taking place.

It has been suggested to remove the empty dialysis solution bag during the dwell period. For example, the Beta-Cap sterile closure sold by the Quinton Instrument Co. is sold for the purpose of capping off CAPD connections so that the patient can remove the bag. However, such a system increases the cost of CAPD, and has not been deemed completely desirable by a majority of physicians.

Bazzato U.S. Patent No. 4,306,976 discloses a system for CAPD in which a set having a Y connection and including a pair of solution containers may be connected to the peritoneal cavity of a patient. One of the containers is empty for receiving spent peritoneal dialysis solution from the patient, while the other container provides peritoneal dialysis solution. The connection with the peritoneal catheter includes a cartridge filled with sterilizing material. While this system permits the patient to go through each dwell period without having to carry a solution container with him, the apparatus adds significantly to the expense of peritoneal dialysis, since it requires the use of one Y shaped set of flexible tubing and two flexible containers with each individual dialysis exchange.

An article by Dr. Umberto Buoncristiani et al. entitled "Abatement of Exogenous Peritonitis Risk Using the Perugia CAPD System" (Dialysis and Transplantation, Volume 12 (1) pp. 14-25 (1983)) discloses a Y shaped, flexible CAPD set which is provided with antiseptic in its interior during the "dwell" period to permit disconnection of dialysis solution bags from the patient during that period, with allegedly reduced risk of peritonitis. Dr. Buoncristiani's method is also discussed in Italian Patent No. 1,033,588, granted August 10, 1979. However, the patient must wear the Y shaped set during the dwell period, there being no provision for its removal by the techniques described above.

In accordance with this invention, a peritoneal dialysis connection set is provided which is removable and storable during the dwell period of the patient, being capable of reuse for an apparently theoretically unlimited number of times, without heightened risk of imparting peritonitis to the patient. As a further advantage, only a single bag or other container of peritoneal dialysis solution is consumed per dialysis exchange, with the former fresh dialysis solution bag being typically retained on the stored peritoneal dialysis

connection set for reuse as the spent dialysis solution container.

Since the set can be reused many times, and there is no increase in usage of peritoneal dialysis solution containers over the currently most popular forms of CAPD. The disconnectability provided by this invention is provided while the process remains substantially as inexpensive as the least expensive current prior art forms of peritoneal dialysis. At the same time, the patient can enjoy freedom from the burden of having to carry a peritoneal dialysis connection set and an empty container during the dwell period.

Description of the Invention

In accordance with this invention a peritoneal dialysis connection set comprises flexible tubing including a central portion of said tubing having a free end. First connector means are carried on the free end and adapted for removable, sealed, flow-through connection with tubing communicating with the peritoneal cavity of a patient, for example the peritoneal catheter.

At least two lengths of branch tubing communicate with the central tubing portion, each of the lengths of branch tubing defining a free end having second and third connector means carried respectively by the free ends of the lengths of branch tubing. The second and third connector means are each adapted for removable, sealed, flow-through connection with a connector communicating with a dialysis solution container so that the connection set is capable of simultaneous communication with two dialysis solution containers.

The first connector is also adapted for removable, sealed connection with either of the second and third connectors so that, upon disconnection from the patient, the first connector is connected with one of the second and third connectors so that the set can be stored while assuming substantially an "U" shaped

configuration. The other of the second and third connectors typically retains its connection with a typically substantially empty container of peritoneal dialysis solution, so that a compact bundle of the set in "U" shaped configuration and the connected empty container can be easily carried by the patient with him in a small briefcase or the like during his dwell period, to be ready for reuse for the next peritoneal dialysis exchange.

Typically, the peritoneal dialysis connection set is substantially filled with a disinfectant, for example, sodium or calcium hypochlorite solution, an iodine solution such as povidone iodine, or any other suitable, known disinfectant. Some of the disinfectant solution can be allowed to reside in the attached dialysis solution container, while substantially the entire interior of the peritoneal dialysis connection set along substantially its entire length is bathed and preferably substantially filled with the disinfectant material. Thus the growth of of bacteria is prevented in the set and desirably the dialysis solution container during each storage period.

For use of the peritoneal dialysis set of this invention, one breaks the connection formed between the first connector and one of the second or third connectors, and causes the first connector to connect to the tubing communicating with the peritoneal cavity of the patient, while connecting the formerly-connected second or third connector with a fresh container of peritoneal dialysis solution (although this last step may be done at a later point in the process if desired).

One then allows spent peritoneal dialysis solution from the peritoneal cavity of the patient to flow through the central portion of the tubing and the branch tubing which communicates with the substantially empty dialysis solution container, to drain the peritoneal cavity of spent dialysis solution. One then clamps shut the branch tubing communicating with this

dialysis solution container, and opens the branch tubing connected with the fresh dialysis solution container. This allows fresh dialysis solution to flow through that branch tubing into the patient's peritoneal cavity while preventing fluid flow through the branch tubing which communicates with the spent dialysis solution container.

One then removes the spent dialysis solution container from connection with its branch tubing for discard, and one removes the central portion of the tubing from its connection with the peritoneal cavity tubing, to expose the two free ends. One then connects those free ends together to restore the set into the "U" configuration. The fresh dialysis solution container is now emptied, and remains connected to the "U" set, with the dialysis solution having been safely administered to the patient.

In the event that the set contains disinfectant, that, of course, must be removed from the interior of the set prior to administering fresh dialysis solution to the patient. This can be done by causing a small amount of fresh dialysis solution to flow through the two branch lines from the fresh dialysis solution container to the empty, spent dialysis solution container, thus washing the disinfectant into the spent dialysis solution container. Also, as spent dialysis solution passes from the patient's peritoneal cavity to the spent dialysis solution container, further washing of the interior of the set is provided.

After the draining and refilling of the patient's peritoneal cavity, the "U" set, with its substantially empty connected container which formerly contained the fresh peritoneal dialysis solution, may be stored until the next dialysis procedure, at which time the process is repeated, with the formerly fresh dialysis solution container assuming the role of the spent dialysis solution container and a new, fresh dialysis solution container being provided for connection with the branch tubing which currently connects with the central portion tubing of the set in its "U" configuration.

Description of the Drawings

Referring to the drawings, Figure 1 is a diagramatic view of the set of this invention connected to a patient, through a peritoneal catheter and a transfer set, and connected to a first bag of peritoneal dialysis solution for administration of the peritoneal dialysis solution to the patient.

Figure 2 is a plan view of the set of this invention in its storage configuration following administration of the peritoneal dialysis solution to the patient and subsequent disconnection.

Figure 3 is a diagramatic view of the set of this invention following reconnection to the patient, and the added connection of a second container of peritoneal dialysis solution, for draining of spent peritoneal dialysis solution from the patient, and readministration of fresh peritoneal dialysis solution to the patient's peritoneal cavity.

Figure 4 is a plan view showing the device of this invention in its alternate storage position, subsequent to disconnection out of the configuration of Figure 3.

Description of Specific Embodiment

Referring to the drawings and particularly to Figure 1, set 10 of this invention is as previously described, including a central portion of flexible tubing 12 having a free end upon which a first tubular connector 14 is carried, capable of receiving a spike member 16 in sealed relationship. Spike member 16 constitutes one end of a flexible transfer set 18, which constitutes flexible tubing carrying a roller clamp 20 or other clamp of known design, and terminating at its other end in a connector 22 of conventional design for sealing with peritoneal catheter 24. Connector 22 may be a conventional plastic double seal connector which connects with a titanium adapter 25 carried on the end of catheter 24, being of a design commonly in current use in peritoneal dialysis.

Tubing 12 communicates with Y connector 26 which, in turn, is connected to two lengths of branch tubing 28, 30 which communicate with central tubing portion 12. Each of said lengths of branch tubing define a free end at which second and third connectors 32, 34 are provided. Connectors 32, 34 in this embodiment are shown to be spike connectors, but may be any connector appropriate for the situation.

As shown in Figure 1, connector 34 is in sealed, flow communication with a first collapsible bag 36 of peritoneal dialysis solution. Accordingly, when clamps 20, 38 are open, and clamp 40 is closed, peritoneal dialysis solution from bag 36 flows through peritoneal catheter 24 into the peritoneal cavity of the patient 42 in a customary procedure of peritoneal dialysis.

Thereafter, clamps 20, 38 may be closed, and connectors 14, 16 may be disconnected. If desired, set 18 may be filled with a disinfectant, such as 0.5 or 1 percent by weight sodium or calcium hypochlorite solution, up to the point of the tube constriction defined by clamp 20, and connector 16 may be capped off with an end cap device such as one similar in structure to tubular connector 14, but with a closed outer end, to seal spike 16 with the disinfectant occupying the outer portion of set 18.

Also, set 10 may be partially or preferably completely filled with a similar disinfectant through tubular connector 14, up to the tube constriction points defined by closed clamps 38, 40 for sterilization of the set. However, a small amount of disinfectant may be allowed to flow into empty bag 36.

Then, as shown in Figure 2, protective cover 43 may be removed and connector 32 may be spiked into connector 14, to place set 10 and attached bag 36 into an "O" shaped configuration with, preferably, antiseptic occupying the interior of the set.

Thus, the set of this invention in the form of Figure 2 may be stored during the "dwell" period, when peritoneal dialysis

solution is residing in the patient. The patient is free from the burden of having to carry a bag or set 10 during this dwell period, and instead only carries a short transfer set 18 connected to catheter 24. Alternatively, catheter 24 itself may be designed to have a connector which connects directly to connector 14 of set 10, eliminating the short transfer set 18. Any appropriate desired design of connectors may be used for this purpose.

When it is desired to remove spent peritoneal dialysis solution from the patient's peritoneal cavity, the connection between connectors 14 and 32 is opened. The sealing cap covering connector 16 is removed, and connectors 14 and 16 are brought together again as shown in Figure 3 in a manner similar to Figure 1. Connector 32 is then connected to a second peritoneal dialysis solution bag 46 so that set 10 now has branch tubing 28, 30 in flow communication with, respectively, bags 46, 36.

Before peritoneal exchange takes place, the disinfectant solution must be removed from the system, to avoid any possibility of disinfectant solution entering the peritoneal cavity. This may be accomplished by opening clamps 38, 40, and allowing a small amount of the fresh peritoneal dialysis solution from bag 46 to flow through branch tubings 28, 30 into container 36, flushing disinfectant along with it.

Thereafter, clamp 40 is closed and clamp 20 opened, to permit spent peritoneal dialysis solution to flow through catheter 24 and set 10 back into the first dialysis solution bag 36 from where it originally came. Disinfectant solution is at the same time washed out of sets 18 and 10 during this process, and deposited in bag 36.

Following this, clamp 38 is closed and clamp 40 opened, so that fresh peritoneal dialysis solution from bag 46 can flow through sets 10, 18, and catheter 24, into the peritoneal cavity.

Following the administration of fresh peritoneal dialysis solution to the peritoneal cavity, the connection between connectors 14, 16 can once again be broken, and connector 16 capped off with a cap of any desired design, optionally placing disinfectant into the outer portion of set 18 as previously described.

Similarly, disinfectant may be placed into set 10 through tubular connector 14, following which connector 34 may be disconnected from the refilled solution container 36, now containing spent dialysis solution and disinfectant, and connectors 14 and 34 may be brought together to put set 10 once again into its "O"-shaped storage configuration as shown in Figure 4. Note, however, that this time it is the opposite branch tubing 30 and its connector 34 which is in storage connection with connector 14, rather than the previously illustrated situation of Figure 2, where branch tubing 28 and connector 32 were in such connection.

At this time, peritoneal dialysis solution container 46 remains attached to set 10 in the storage mode, being substantially emptied of peritoneal dialysis solution, but optionally containing a small amount of the disinfectant solution applied through connector 14 prior to forming the O configuration. As before, the patient is free to engage in his activities throughout the dwell period of solution in his peritoneal cavity without having to carry a bag or set 10.

Thereafter, when once again it is desired to make an exchange, set 10 in the storage configuration of Figure 4 can be once again opened to break the connection between connectors 14 and 34. Connector 14 is reconnected to set 18 through connector 16 (or directly to catheter 24 when such circumstances warrant it), and connector 34 is in turn connected to yet another container of fresh peritoneal dialysis solution. The drainage process is repeated with an initial flush of a small amount of fresh dialysis solution passing through branch tubings 30, 28 to

flush disinfectant into empty bag 46. The spent peritoneal dialysis solution is then drained through catheter 24 and set 10 into bag 46, following which fresh peritoneal dialysis solution passes through branch tubing 30 into the peritoneal cavity.

Following the reinfusion of fresh peritoneal dialysis solution, connector 32 is disconnected from the refilled bag 46 of spent peritoneal dialysis solution and reconnected to connector 14, to cause the device to once again assume the storage configuration similar to that shown in Figure 2.

This process is repeated indefinitely from exchange to exchange, with set 10 being reusable for whatever period of time is deemed feasible and desirable. Typically set 10 may be reused with approximately four exchanges per day in a CAPD patient for a period in excess of one week, up to six months or more.

By the method and apparatus of this invention, the patient is freed from being tied to a solution container, which is burdensome and unpleasant even when the container is a collapsible bag, as is typical. The patient is also freed from continuous attachment to set 10, so that the only permanent equipment he must carry is the catheter and, where deemed necessary or desirable, the transfer set.

Through the use of a disinfectant as described herein, the risk of peritonitis can be significantly reduced, for an effective system of maintenance of a patient by peritoneal dialysis.

The above has been offered for illustrative purposes only, and is not intended to limit the scope of the invention of this application, which is as defined in the claims below.

THAT WHICH IS CLAIMED IS:

1. A peritoneal dialysis connection set which comprises flexible tubing including a central portion of said tubing having a free end, first connector means carried on said free end and adapted for removable, sealed, flow-through connection with tubing communicating with the peritoneal cavity of a patient; at least two lengths of branch tubing communicating with said central tubing portion, each of said lengths of branch tubing defining a free end; second and third connector means carried respectively by the free ends of said lengths of branch tubing; said second and third connector means being each adapted for removable, sealed, flow-through connection with a connector communicating with a dialysis solution container; said first connector being also adapted for removable, sealed connection with either of said second and third connectors.

2. A peritoneal dialysis connection set which comprises flexible tubing including a central portion of said tubing having a free end, first connector means carried on said free end and adapted for removable, sealed, flow-through connection with tubing communicating with the peritoneal cavity of a patient; at least two lengths of branch tubing communicating with said central tubing portion, each of said lengths of branch tubing defining a free end; second and third connector means carried respectively by the free ends of said lengths of branch tubing; said second and third connectors being each adapted for removable, sealed, flow-through connection with a connector communicating with a peritoneal dialysis container; said first connector being also adapted for removable, sealed connection with either of said second and third connectors, said first and second connectors being in said removable, sealed connection relation; and a dialysis solution container having a connector in removable, sealed connection relation with said third connector.

3. The peritoneal dialysis connection set of Claim 2 in which said dialysis solution container is substantially empty of peritoneal dialysis solution.

4. The peritoneal dialysis connection set of Claim 3 in which said dialysis solution container is collapsible.

5. The peritoneal dialysis connection set of Claim 3 in which said set is at least partially filled with disinfectant.

6. The method of performing peritoneal dialysis which comprises connecting a flexible tubing set, including a central portion of said tubing having a free end, to tubing communicating with the peritoneal cavity of the patient; allowing spent peritoneal dialysis solution from the peritoneal cavity of the patient to flow through said central portion of said tubing, and through a first branch tubing communicating with the central tubing portion, into a first dialysis solution container connected to said first branch tubing while flow is prevented through a second branch tubing communicating with the central tubing portion; allowing fresh dialysis solution to flow from a second container of fresh dialysis solution through the second branch tubing into the patient's peritoneal cavity while preventing fluid flow through said first branch tubing; removing the first dialysis solution container from connection with said first branch tubing and removing the central portion of said tubing from its connection with the tubing communicating with the peritoneal cavity of the patient to expose free ends thereof; and connecting the free end of said first branch tubing with the free end of said central portion of the tubing to store said peritoneal dialysis connection set separate from the patient, while retaining connection between the second branch tubing and the second container.

7. The method of Claim 6 in which said set is at least partially filled with disinfectant prior to storing said set separate from the patient.

8. The method of Claim 6 in which said method is repeated, with the second branch tubing and second dialysis solution container assuming the role of the first branch tubing and first dialysis solution container, and said first branch tubing is connected to another container of fresh dialysis solution.

9. The method of Claim 6 in which, prior to repeating said method, some fresh dialysis solution from said other container is shunted through the first branch tubing and second branch tubing into the second dialysis solution container to remove said disinfectant, and allowing said spent peritoneal dialysis solution from the peritoneal cavity of the patient to flow through the central portion of the tubing and said second branch tubing into the second dialysis solution container while flow is prevented through the first branch tubing, for removal of substantially all disinfectant from the set.

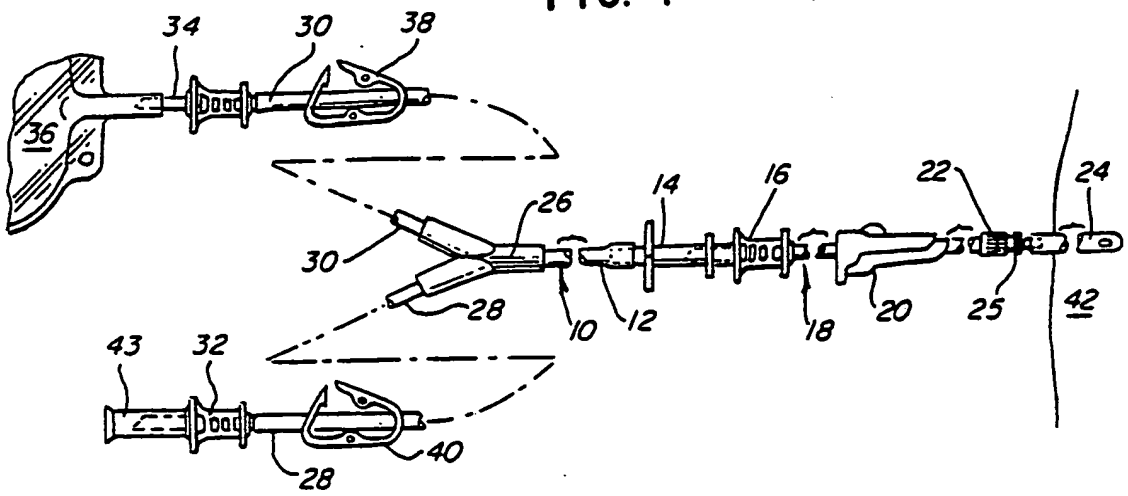
10. The method of Claim 6 in which said dialysis solution containers are collapsible containers.

11. The method of Claim 10 in which said flexible tubing set is reused for a period in excess of one week.

12. The method of Claim 6 in which said set is at least partially filled with disinfectant prior to storing said set separate from the patient, and in which said method is repeated with the second branched tubing and second dialysis solution container assuming the role of the first branch tubing and first dialysis solution container, and said first branch tubing is connected to another container of fresh dialysis solution, and

in which, prior to repeating said method, some fresh dialysis solution from said other container is shunted through the first branch tubing and second branch tubing into the second dialysis solution container to remove said disinfectant, and said spent peritoneal dialysis solution flows from the peritoneal cavity of the patient to flow through the central portion of the tubing and said second branch tubing into the second dialysis solution container while flow is prevented through the first branch tubing, for removal of substantially all disinfectant from the set, said dialysis solution containers being collapsible bags.

FIG. 1



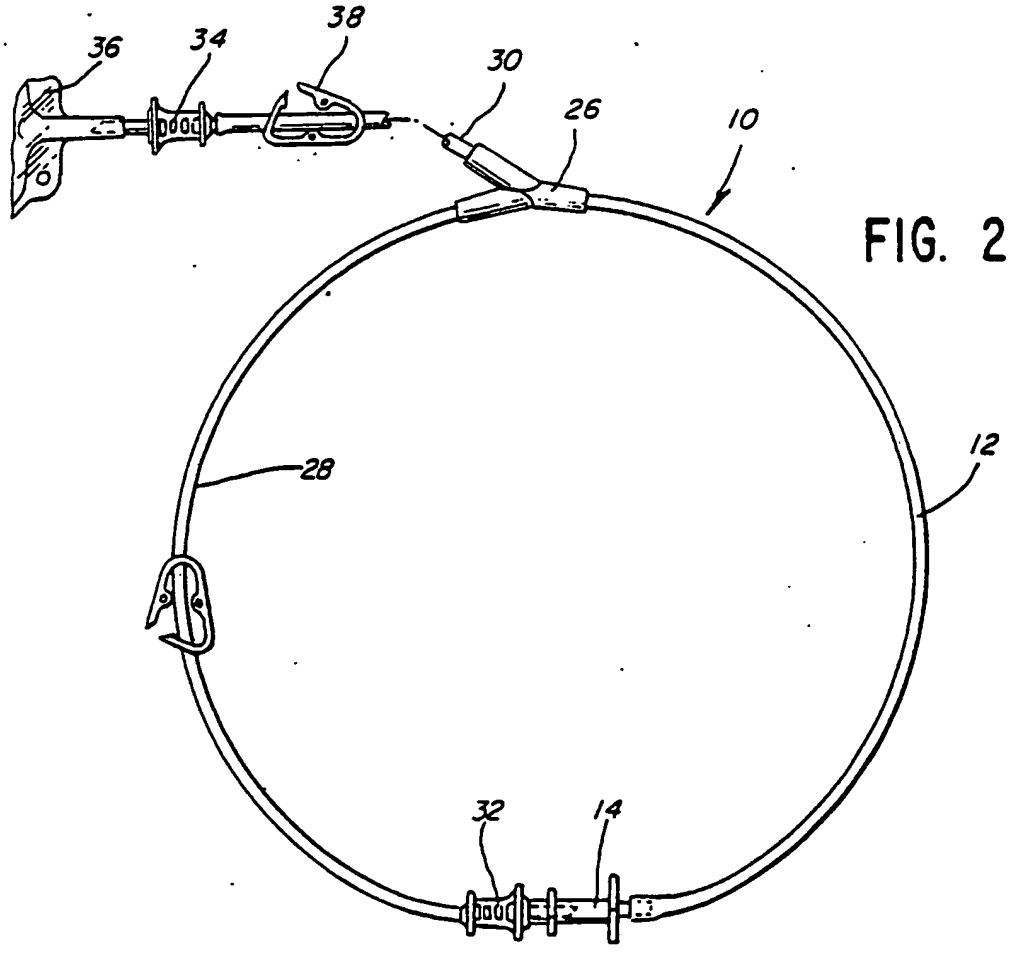
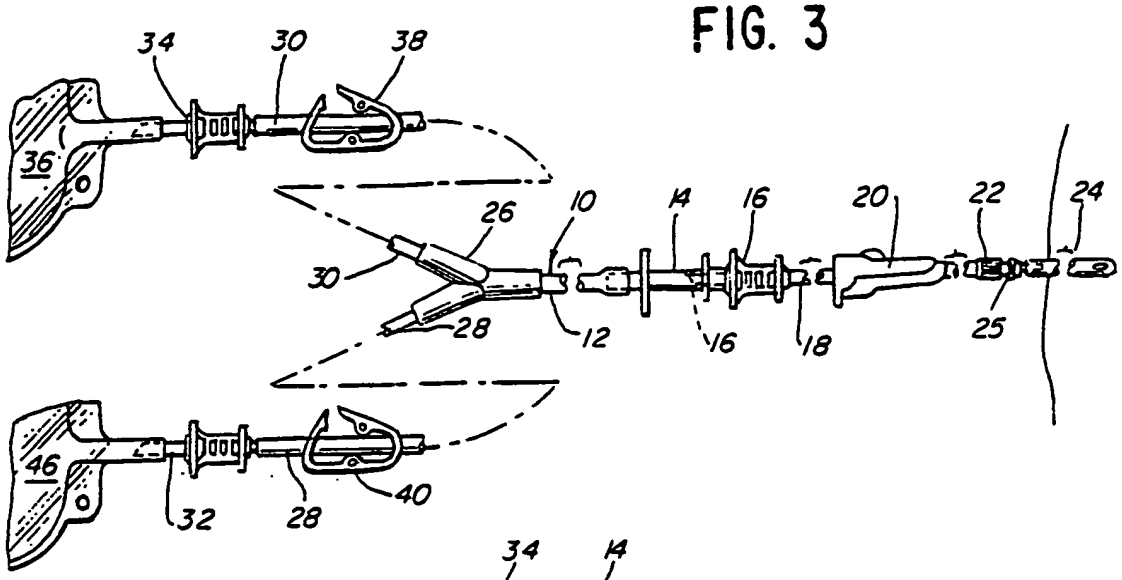


FIG. 2

FIG. 3



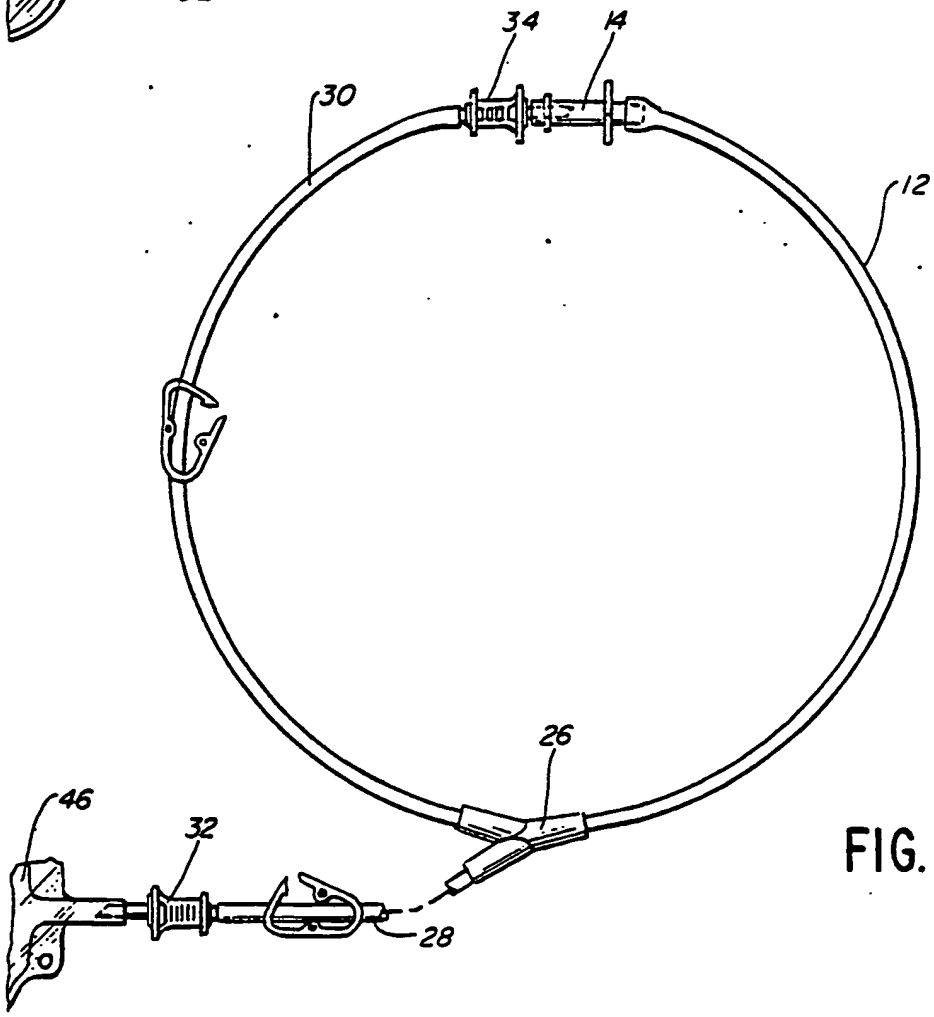


FIG. 4

INTERNATIONAL SEARCH REPORT

International Application No PCT/US84/01480

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

US: 604/28, 29 IPC: [9] A61M 5/00

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
US	604/28, 283, 410, 905, 80-81, 86, 408, 29

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [6]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]		Relevant to Claim No. [18]
A	US, A, 2,452,643	02 November 1948 (FIELDS) (02.11.48)	
A	US, A, 3,599,641	17 August 1971 (SHERIDAN) (17.08.71)	
A	US, A, 4,294,250	13 October 1981 (DENNEHEY) (13.10.81)	
X, Y	US, A, 4,396,382	02 August 1983 (GOLDHABER) (02.08.83)	(1-4, 6, 8, 10-11); (5, 7, 12)
Y, P	US, A, 4,432,764	21 February 1984 (LOPEZ) (21.02.84)	(5, 7, 12)
Y	US, E, Re. 25,129	27 February 1962 (WALTER) (27.02.62)	(1-2, 6)

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
24 October 1984	13 NOV 1984
International Searching Authority [1]	Signature of Authorized Officer [20]
ISA/US	C. Fred Rosenbaum

Form PCT/ISA/210 (second sheet) (October 1981)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]

This International search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers _____, because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers _____, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]

This International Searching Authority found multiple inventions in this international application as follows:

I. A peritoneal dialysis connection set: Claims 1-5

II. A method of performing peritoneal dialysis: Claims 6-12

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☒ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.